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STATE OF DELAWARE

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PUBLIC MEETING NOTICE:	**CONTROLLED SUBSTANCE COMMITTEE**
DATE AND TIME:	**Wednesday, March 25, 2015 at 9:00 a.m.**
PLACE:	**Buena Vista Conference Center, Dining Room, First Floor, 661 S. DuPont Highway, New Castle, Delaware 19720**
APPROVED:	**Approved May 27, 2015**

MEMBERS PRESENT

Luis Garcia, Jr., DPM, Podiatric Representative, Vice President
Stephen Ruggles, PA-C, PA Representative
Art Jankowski, VMD, Veterinary Representative
Herb E. Von Goerres, R.Ph., Pharmacy Representative
Jo Ann M. Baker, MSN, RN, FNP-C, Nursing Representative
Mark Hanna, Public Representative

MEMBERS ABSENT

Michael Kremer, DMD, Dental Representative, President
Philip Kim, M.D., Medical Representative
Alex Zarow, R.Ph., Pharmacy Representative

DIVISION STAFF/DEPUTY ATTORNEY GENERAL

David W. Dryden, R.Ph., J.D., Director, Office of Controlled Substances
Christine Mast, Administrative Specialist III
Eileen Kelly, Deputy Attorney General
David Mangler, Director, Division Professional Regulation
Samantha Nettesheim, Pharmacist Administrator

ALSO PRESENT

Jeff Whitmarsh
Letitia Kanar
Ray Hancock
Debbie Hamilton
Lucy Somer
Phil Anderson

CALL TO ORDER

Mr. Von Goerres called the meeting to order at 9:06 am.

REVIEW AND APPROVAL OF MINUTES

A motion was made by Dr. Jankowski, seconded by Mr. Hanna, to approve the minutes from the November 5, 2014 meeting as amended. The motion was unanimously carried.

PRESIDENT'S REPORT
No Report

UNFINISHED BUSINESS
None

NEW BUSINESS
Mr. Dryden wanted to make the committee aware of an application received for a rehabilitation facility located in Middletown, De. that will utilize the CII Pyxis Safe. The model of the safe has a glass front. Mr. Dryden did an inspection of the facility and the unit to ensure that it met the standards and requirements of the law. Mr. Dryden approved the unit that is located in a locked pharmacy with security cameras and limited access and requested that the unit be bolted to the floor.

Mr. Dryden stated that the 1 hour continuing education credit required of practitioners has been completed. There are two avenues to complete the 1 hour course. It is available on the Division of Professional Regulations website free of charge and it is also available on the Medical Society Website for a nominal fee. All practitioners are required to complete the course.

Review of Advanced Practice Nurse Application: Maureen Gay Johnson. A motion was made by Mr. Ruggles and seconded by Mr. Hanna to approve the application. Ms. Baker recused herself. The motion carried.

A motion was made by Dr. Garcia and seconded by Mr. Hanna to move ahead in the agenda. The motion unanimously carried.

Review of Physician Assistant Application: Meghan Vande Logt, PA-C. A motion was made by Dr. Jankowski and seconded by Ms. Baker to propose to deny the application. The motion carried unanimously.

DIRECTOR'S REPORT
Mr. Dryden reported that the division has been supporting a number of ongoing investigations from complaints. There has been an increase in diversion cases in hospital and nursing facility settings.

Mr. Dryden has been working with NASCSA on safe opioid prescribing practices.

Case/Diversion Review
None

PMP Review
Ms. Nettesheim reported that in 2013 the Division of Professional Regulation contracted with Brandice University to provide data analysis on our PMP information. We provide them de-identified data for analytical purpose. They are currently providing 25 different templates of analysis. We can also request specialized analytical information not provided in the 25 templates. This is provided at no cost through the Bureau of Justice. Ms. Nettesheim provided analytical data showing quarter 2 of 2012 through the end of 2013 opioid dispensing remained the same.

Ms. Nettesheim provided chart #1 which shows "Quarterly Prescription Rates for Opioids"'' in Delaware from quarter #2 of 2012 through the end of the year 2013. The chart showed that rates for Delaware were above the 7 other collaborating states. However, dispensing remained the same in Delaware and was the same for the 7 collaborating states combined. There were many discussions of a report released last year that Delaware ranked #1 of dispensing of long acting opioids nationally. The dispensing rate does not necessarily indicate abuse or diversion. Delaware has a high incidence of cancer that could directly affect dispensing rates reported.

Ms. Nettesheim presented chart # 2 which was ‘’Multiple Provider Episode Rates”. This is defined as patients receiving multiple prescriptions for controlled substances from 5 different pharmacies and 5 different prescribers for Delaware only. The chart shows a reduction in patients receiving opioids, stimulants, and benzodiazepines from multiple providers and pharmacies. This indicates possible reductions in diversion. However, there are indications that patients are still receiving multiple prescriptions from multiple providers and they are crossing state lines to have them filled at other pharmacies.

Ms. Nettesheim stated that there have been a lot of discussions regarding increased heroin use and the PMP. DSAM reported that heroin treatment admission started to increase in 2012. However, the PMP was not implemented until the last quarter of 2012. It is highly unlikely that the PMP would have attributed to the increase in admissions in that short amount of time.

Current Event Review

Coalition Targets Abuse of ADHD Meds

A new coalition has formed to help prevent the misuse, abuse, and diversion of medications for the treatment of attention-deficit/hyperactivity disorder (ADHD), particularly among college students. (CPAMM) members include the American Academy of Family Physicians, Children and Adults with Attention-Deficit Hyperactivity Disorder (CHADD), the Jed Foundation, NASPA – Student Affairs Administrators in Higher Education, the BACCHUS Initiatives of NASPA, and Shire. CPAMM’s focus will be research and educational programs. It plans to study the perceptions and attitudes of college students regarding ADHD prescription stimulant misuse and abuse. That research will be used to design educational campaigns to prevent nonmedical use.

States with Medical Marijuana Have Fewer Prescription Opioid Overdose Deaths, Study Claims

Annual rates of overdose deaths related to prescription painkillers are an average of 24.8% lower in states with medical marijuana programs, a new study indicates. The researchers also found that such programs are associated with significantly lower opioid overdose mortality rates, and that the lower rate of overdose mortality strengthened over time. The authors of the study note that their analysis did not account for differences in health attitudes from state to state that could contribute to the correlation, according to Smithsonian. Critics contend that the study failed to examine the influence of other prevention and treatment measures such as expanded methadone and buprenorphine programs, reports CNN. The study “Medical Cannabis Laws and Opioid Analgesic Overdose Mortality in the United States, 1999-2010,” is available on the JAMA Internal Medicine website.

DEA Finalizes Rule on Controlled Substance Prescription Drug Disposal

Drug Enforcement Administration (DEA) has published its Final Rule on Disposal of Controlled Substances, allowing some DEA registrants to modify their registration to become authorized collectors. The Final Rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances, for disposal purposes, a DEA press release notes. Under the new rule, some DEA registrants, including manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies, and hospitals/clinics with an on-site pharmacy, may modify their registration with DEA to become authorized collectors. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The Final Rule will take effect on October 9, 2014.

National Decline in Rates of Prescription Drug Abuse in 2013, SAMHSA Reports

The number of people abusing prescription medications decreased from 6.8 million users in 2012, to 6.5 million users in 2013, according to the latest National Survey on Drug Use and Health (PDF). The

annual report, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), also found that rates of prescription drug abuse among adolescents (aged 12 to 17) decreased from 2.8% to 2.2%, continuing a gradual decline from a rate of 4% in 2002. The overview report and an infographic summarizing the information are available on the SAMHSA website. Safely disposing of unneeded medications is one way to help fight prescription drug abuse. Individuals wishing to help in this effort can participate in the next DEA National Prescription Drug Take-back Day, scheduled for Saturday, September 27, 2014.

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations
Martin Avenue Pharmacy, Inc, of Naperville, IL, has issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance. Following a recent Food and Drug Administration (FDA) inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution. The Delaware Board of Pharmacy does not have this Pharmacy licensed under our Pharmacy Act.

FDA to Host Public Meeting on Development and Regulation of Abuse-Deterrent Opioid Medications
FDA will host a public meeting to discuss the development, assessment, and regulation of abuse-deterrent formulations of opioid medications. "The meeting will focus on scientific and technical issues related to the development and in vitro assessment of these products," notes an FDA announcement. FDA's assessment approach for determining the benefits and risks of opioid medications will also be discussed. The meeting will be held on October 30-31, 2014, in Silver Spring, MD, and FDA will post registration information to its website soon.

FDA Publishes 'Purple Book' of Licensed Biological Products and Interchangeable Biosimilars
FDA has released the "Purple Book," new documents listing biological products, including all biosimilar and interchangeable biological products licensed by FDA. The lists include the date a biological product was licensed and whether FDA evaluated the biological product for reference product exclusivity, as defined under the Public Health Service Act. The Purple Book will also list whether a licensed biological product has been determined to be biosimilar to or interchangeable with a reference biological product. Separate lists for those biological products regulated by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research will be updated periodically.

FDA Issues New Warning Against Using NuVision Pharmacy Products
Sterile-use drug products produced and distributed by Downing Labs, LLC, of Dallas, TX, doing business as NuVision Pharmacy, may not be safe, and should not be used, Food and Drug Administration (FDA) warns in a press release. Following the results of a July 2014 inspection, the agency issued a formal request (PDF) to Downing Labs for the immediate recall of all lots of medication marketed as sterile, citing concerns about facility conditions and practices and the sterility assurance of the drug products. The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate investigation into these failures.
Follow up discussions with NuVision representatives have determined that no sterility failed products have been sent to Delaware. NuVision has been licensed as a non-resident pharmacy in Delaware since 04/12/12.

Pharmacy Creations Recalls Four Lots of Products Due to Sterility Concerns
Pharmacy Creations of Randolph, NJ, has issued a voluntary recall of four lots of products after testing results found potential for lack of sterility. Although the company has not confirmed contamination and there have been no reported adverse events associated with the use of the products, the recall is being

initiated out of an abundance of caution to ensure patient safety, indicates a press release. The recalled products are:

- Ascorbic Acid, 500 mg/mL, 50 mL vial,
  Lot 05082014@7, Expiration 11-4-2014
- Glutathione, 100 mg/mL, 30 mL vial,
  Lot 05122014@4, Expiration 9-9-2014
- Magnesium Chloride, 200 mg/mL, 50 mL vial,
  Lot 05202014@7, Expiration 11-19-2014
- Tropi/Cyclo/Phenyl/Tobra/Flurb, 1%/1%/10%/0.3%/0.3%, 3 mL vial, Lot 05202014@3, Expiration 11-16-2014

These products were distributed in Florida, New Jersey, New York, and Puerto Rico between March 4, 2014, and June 18, 2014 and were mailed directly to patients and health care providers. They were not distributed to Delaware. They have been licensed as a non-resident pharmacy in Delaware since 06/19/14. Physicians and patients that have these products should stop use and return to the place of purchase.

White House Releases National Strategy for Combating Antibiotic-Resistant Bacteria

Citing the Centers for Disease Control and Prevention (CDC) finding that antibiotic-resistant bacterial infections are responsible for an estimated 23,000 deaths each year, the White House has released a document detailing a national strategy to curb antibiotic-resistant bacteria. The *National Strategy for Combating Antibiotic-Resistant Bacteria* (PDF) includes educational efforts for patients, pharmacists and other health care providers, and other stakeholders to minimize unnecessary prescribing of antibiotics, among other initiatives. The strategy document is the basis of a 2014 Executive Order on Combating Antibiotic Resistance, as well as a forthcoming *National Action Plan* that directs federal agencies to accelerate the response to "this growing threat to the nation's health and security

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs through a new educational program known as Know Your Source. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring all drugs received are FDA-approved medications.

Study: Opioid Prescriptions Tied to 92,000 Overdoses in ERs

A study published in JAMA Internal Medicine on Oct. 27 revealed an estimated 92,200 hospital visits nationwide in 2010 as a result of prescription painkiller overdoses. The study found that 68 percent of all opioid-related overdoses that were treated in hospital ERs involved prescription painkillers, and caring for these patients cost hospitals around $1.4 billion. The study's authors noted that the problem of prescription painkiller overdoses, while rarely fatal, is a significant drain on the nation's healthcare system. According to researchers from Stanford University, the University of Pennsylvania, Brown University and Rush Medical College, 55 percent of patients who went to the ER for an opioid overdose were admitted, with an average stay of 3.8 days and average charges of $29,497. For the 41 percent of patients who were released without being admitted, the average charges were $3,640. Moreover, 40 percent of patients needing emergency care for prescription painkiller overdoses were from the South, 66 percent were aged 18 to 54 and 79 percent lived in ZIP codes where the median income was less than $67,000.

Los Angeles Times (10/27/14) Girion, Lisa; Kaplan.

Final Prescription Drug Take-Back Day Collects 617,150 Pounds of Unwanted Medications

Over 600,000 pounds of unneeded, unwanted, or expired prescription medications were properly disposed of during the final Drug Enforcement Administration (DEA) National Prescription Drug Take-Back Day, held September 27, 2014. DEA and its law enforcement partners provided 5,495 collection sites across all 50 states, the District of Columbia, and United States territories, DEA Reports. Following the release of DEA's recently published final rule on the disposal of controlled substances, the agency announced that this would be the last DEA Prescription Drug Take-Back Day. After nine events, DEA has collected more than 4.8 million pounds of unwanted medication for safe and secure disposal.

WHO Recommends Increased Naloxone Access Worldwide

The World Health Organization (WHO) has released new guidelines aimed at reducing the number of opioid-related deaths globally. The recommendations include expanding access to naloxone, the drug that can help to reverse the effects of an opioid overdose, for people who are most likely to witness an overdose in their communities, including friends, family members, and partners of people who are most at risk. In most countries, naloxone is currently accessible only through hospitals and ambulance crews who may not be able to administer the drug in time to prevent an injury or death related to an overdose. In October 2014, NABP issued a policy statement promoting an active role for pharmacists in expanding access to the drug.

BJA Releases Naloxone Tool Kit

On Monday, October 27, 2014, the Bureau of Justice Assistance (BJA), Office of Justice Programs, U.S. Department of Justice released its online Law Enforcement Naloxone Toolkit, a free, comprehensive "guide for state, local, and tribal agencies interested in establishing an overdose reversal program using naloxone." Containing more than 80 resources, it provides templates that can all be downloaded to one's computer and customized to the needs of a specific department or community as well as data collection forms, standard operating procedures, training guides, community outreach materials and memoranda of agreement..

FDA Approves New Abuse-Deterrent Single-Entity Hydrocodone Product

FDA has approved a new opioid analgesic medication with abuse-deterrent properties that make the drug difficult to crush, break, or dissolve. The new medication, Hysingla® ER (hydrocodone bitartrate) is an extended-release medication intended to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The abuse-deterrent properties are expected to reduce, but not entirely prevent, abuse of the drug when chewed and then taken orally, or crushed and snorted or injected. The agency notes, however, that abuse of Hysingla ER by these routes is still possible, and that taking too much can still lead to an overdose that may result in death.

Prescriptions for Anxiety, Sleep Medications Expose Teens to Abuse Risk

Teenagers prescribed sleep or anxiety medications such as Lunesta® or Xanax® are at greater risk of abusing those drugs than adolescents who have never been prescribed such medications, reports new research published in the journal Psychology of Addictive Behaviors. Researchers from the University of Michigan surveyed more than 2,700 middle and high school students from 2009 to 2012. Students who had been prescribed anxiety medications before the study began and did not have a current prescription were 12 times more likely to abuse the drugs than students who had never been prescribed the drugs. Those who abused the medications often obtained pills illegally from family and friends, the researchers reported. More than 3% of students had a current prescription during the study, and they were 10 times more likely to abuse the drugs. Additionally, students were more likely to abuse

medications if they were white, female, and had obtained a valid prescription for several years. Delaware has routinely had high usage and abuse trends associated with Xanax (alprazolam).

Zohydro Extended Release Approved

Zogenix Inc. has received U.S. approval for a new formulation of its much-debated painkiller Zohydro that is intended to be harder to abuse, though the company is still working on studies needed to promote that claim. The Food and Drug Administration late Friday approved new Zohydro Extended Release capsules which are designed to form a thick gel when crushed or dissolved in liquid. People who abuse prescription painkillers typically crush or dissolve them for snorting or injecting. Zogenix said it will replace the currently available version of the drug with the new formulation during the second quarter of the year. Despite the new design, Zohydro's label will not yet carry any claims that the drug is more difficult to abuse. The FDA requires drug makers to submit clinical data demonstrating abuse-deterrent properties before promoting them to doctors or patients.

President Obama Requests Historic Levels of Funding for Public Health Responses to Illicit Drug Use

President Obama proposed critical investments to help combat the growing problem of opioid addiction throughout the country. The Administration's FY 2016 Budget for the Department of Health and Human Services includes new funding for CDC to address opioid abuse. $48 million in new funding to strengthen and evaluate state-level prescription drug overdose prevention, including a major expansion of the Prescription Drug Overdose Prevention for States program to support efforts to reduce overdoses from opioids, as well as from other drugs. $5.6 million in new funding for the CDC to address the rising rate of heroin-related overdose deaths by working to collect near real-time emergency department data and higher quality and timely mortality data by rapidly integrating death certificate and toxicology information. $5 million in increased funding for electronic death reporting to provide faster, better quality data, including on opioid overdose deaths. The FY 2016 Budget for HHS's Substance Abuse and Mental Health Services Administration SAMHSA) includes $12 million for a new program to provide grants to 10 states to significantly reduce the number of opioid overdose-related deaths and help states purchase naloxone, equip and train first responders in high-risk communities on its use, support education on the use of naloxone and other overdose death prevention strategies, and support dissemination efforts.

Medicine Abuse Project Shows Connection Between Prescription Pain Killer Abuse and Heroin Addiction

More than half of teens and young adults who inject heroin first abused prescription drugs, a new infographic from the Partnership for Drug-Free Kids emphasizes. The graphic, titled "From Rx to Heroin," illustrates the path taken by a teen from injury and legitimate prescription drug use, to eventual heroin addiction. "The sad truth is that some young people start on a journey abusing prescription painkillers and then switch to heroin because it's actually cheaper and more accessible," notes the president of the Partnership for Drug-Free Kids in a press release posted to the organization's website. "Our hope is that parents will start a dialogue about what steps they can take to help prevent prescription painkiller abuse in their own families."

COMMITTEE REPORTS

Medical Examiner's Report

No report.

DEA Report

No report.

Substance Abuse Report
No Report

Law Enforcement Report
Mr. Jeff Whitmarsh addressed the committee to inform them of a new option for reporting diversion available through the Delaware State Police. He provided the committee a brochure with the information. Mr. Whitmarsh stated that information previously provided to pharmacists instructed them to contact the DEA in Philadelphia, PA whenever diversion occurred. This was problematic due to the number of investigations conducted by the DEA in the Philadelphia, PA office. So instead pharmacists are to contact the Delaware State Police when diversion occurs.

Secondly, Mr. Whitmarsh reported that the Drug Diversion Unit will be directly responsible for the new medical marijuana facility being built in New Castle County. The tentative opening date of the facility is June 1, 2015. There are currently 350 medical marijuana card holders in the state of Delaware.

Regulatory Committee Report
Mr. Dryden reported that the regulatory committee met and discussed safe opioid prescribing concerns. They discussed draft proposed regulation 11.0 Safe Opiate Prescribing and reviewed suggestions and comments received from the Medical Society, PDAC, Manufacturers, Patient Advocates and the Oncology Society. The committee prepared draft proposed regulations. Mr. Dryden also provided an example of Safe Opioid Prescribing practices that were developed by Oregon for the committee to review. Mr. Mangler expressed concern from the Medical Society that the definition of chronic pain in regulation 18.0 of the Board of Medical Licensure and Discipline is different than that in the draft regulation 11.0 Controlled Substances Regulation. The definition needs to be consistent in both. Mr. Dryden stated he would make the correction.

Legislative Committee Report
Mr. Dryden made the committee aware that a law had passed and was awaiting the governor's signature to exclude veterinarians and methadone clinics from the statutory requirement of limiting the dispensing of controlled substances to 72 hours.

INSPECTION REPORT
None

COMMITTEE CORRESPONDENCE
Mr. Dryden provided handouts on the following to the committee for review:
CBS-Investigation Insurance Billed $18 for unwanted pain medications, Zogenix gets approval for new version of painkiller, Alert provided to pharmacy providers regarding; Medicaid revisions to RX BIX, RX PCN and Group/Customer number changes.

OTHER BUSINESS BEFORE THE BOARD
Non-Photo ID cards; Ms. Kelly reported that current regulations do not allow a means for an alternative acceptable identification other than photo id. A.I. Dupont Hospital for children has expressed concern for their Amish patients and their inability to provide photo id due to their religious beliefs. Historically if a photo id is required to receive medication they ask someone with a photo id to pick up their medications. State Bureau of Identification will provide finger prints and Kent County provides non-photo ID cards to the Amish community. Mr. Danny Hall at SBI has the information on the procedure for the Amish to get a non-photo-id card. Ms. Kelly stated to except this type of ID card would require a rule and regulations changes to permit the use of this ID card.

PUBLIC COMMENTS
None

EXECUTIVE SESSION
None

NEXT SCHEDULED MEETING
The next regular meeting will be held on May 27, 2015 at 9:00 am at the Buena Vista Conference Center, Buck Library.

ADJOURNMENT
A motion was made by Mr. Hanna, seconded by Mr. Ruggles, to adjourn the meeting. The motion unanimously carried. The meeting adjourned at 10:16 am.

Respectfully submitted,

Christine Mast
Administrative Specialist III
Office of Controlled Substances